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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,557	05/24/2001	Scott Hammond	CSHL-P02-010	4804

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ROPES & GRAY LLP
PATENT DOCKETING 39/41
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MCGARRY, SEAN	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/866,557	HAMMOND ET AL.	
	Examiner	Art Unit	
	/Sean R. McGarry/	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/09/07, 6/28/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,12,14,28 and 47-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 12, 14, 28, 47-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/28/07;7/25/07;8/14/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Official Action is mailed in response to the papers filed 3/09/07 and 6/28/07. All rejections not repeated from the previous Official Action are withdrawn.

Claim Rejections - 35 USC § 112

Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant adds new claim 49 with their response. Claim 49 recites a size limitation of "20 to 50 base pairs in length". Applicant point to paragraph [0017] for support. It is noted that the context of the specification does not lend to the formation of the range instantly recited. The specification provides for dsRNA "at least 20" or "at least 50", for example. The use of "at least" indicates a lower limit. The use of 50 as an upper limit is not consistent with the specification and constitutes new matter where it is not disclosed nor made apparent by the disclosure of the specification that such a specific range was intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 12, 14, 15, 28, and 47-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al [US 6,506,559].

Fire et al disclose a method to inhibit expression of a target gene in a cell in vitro comprising the introduction of a ribonucleic acid into the cell in an amount sufficient to

inhibit expression of the target gene, wherein the RNA is a double-stranded molecule with a first strand consisting essentially of a sequence of he target gene and a second strand consisting essentially of a sequence that is complementary to the nucleotide sequence of the target gene.

The target gene may be a gene derived from the cell or a gene of a pathogen which is present in the cell [column4, line28-30, for example]. The double-stranded RNA structure may be formed by a single self-complementary RNA strand [column 4, lines 41-45; and column 7, lines 42-52, for example]. Inhibition is disclosed as being sequence specific [column 4, lines 50-51, for example]. The cell with the target gene can be derived from mammals such as primates including humans [column 8, lines13-51, for example]. The double stranded RNA can be expressed from a vector [columns 4-5, and column 8, line 62- column 9, line25, for example]. It is disclosed that RNA containing sequences that are identical to a portion of the target gene are preferred [see column 7, line53- column 8, line 12, for example]. Fire et al indicate that the level of inhibition is dependent on the dose [column 7, for example]. At column 8 and claim 10 it is disclosed that the double stranded RNA can be at least 25 [which includes 25] nucleotides in length.

Fire et al meet all of the structural limitations for the compound required in the instant claims. Any functional limitations such as being a substrate for RNAse III, not producing a general sequence independent killing in mammalian cells (PKR response) and inhibition by at least 5 fold and the dsoligonucleotides being targets for Dicer are presumed by the examiner to be present in the structures disclosed by Fire et al since

they meet all of the structural requirements of the claims. If applicant believes that there is/are specific structures that provide for these properties of the claimed method and are not disclosed by the prior art applicant should point to those structures of their claimed invention as they pertain to mammalian cells.

Applicant is reminded:

> **A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION,
> AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE
> APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE**
>
> **"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).**
>
> **MPEP 2112.01:**
>
> **PRODUCT AND APPARATUS CLAIMS X WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT**
>
> **Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). AWhen the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.≅ *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.**

**A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE
PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC**

**Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35
U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of**

function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Claims 1, 12, 14, 15, 28, and 47-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al [US 2002/0114784 A1].

Li et al disclose A method for attenuating the expression of a target gene in a cell comprising introducing into the cell a double stranded RNA in an amount sufficient to attenuate expression of the target gene, wherein the double stranded RNA comprises a nucleotide sequence that is essentially identical to the nucleotide sequence of at least a portion of the target gene [claim 1, for example]. The target gene can be endogenous or the target gene can be foreign [claims 2 and 3 and paragraph 32, for example]. The cell can be a mammalian cell including a human cell [claim 11 and paragraph 33, for example]. The double stranded RNA can comprise a sequence that is completely identical to the nucleotide sequence of at least a portion of the target gene [claim 15, for example]. The double stranded RNA can be formed from one strand to take the form of a self-complementary hairpin-type molecule that doubles back on itself to form a duplex [paragraph 36, for example]. The cells can be in culture [paragraph 6 and 44-46, for example]. The double stranded RNA can be delivered to cell via vectors [paragraphs 45 and 46, for example]. It is disclosed at paragraph [0039] that the dsnucleic acids can be at least 25 [which includes 25] bases in length.

Li et al meet all of the structural limitations for the compounds required in the instant method claims. Any functional limitations such as being a substrate for RNAse III, not producing a general sequence independent killing in mammalian cells (PKR

response) and inhibition by at least 5 fold and being a substrate for Dicer are presumed by the examiner to be present in the structures disclosed by Li et al since they meet all of the structural requirements of the claims. If applicant believes that there is/are specific structures that provide for these properties of the claimed method and are not disclosed by the prior art applicant should point to those structures of their claimed invention as they pertain to mammalian cells.

Applicant is reminded:

> **A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION,**
> **AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE**
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> **"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).**
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Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly

disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Applicant's arguments filed 3/09/07 have been fully considered but they are not persuasive. Applicant argues the 102 references are not eligible as prior art. Applicant argues that the prior art must at least substantially identify the species and its properties to constitute anticipation where it is also stated that if it is possible to derive a class of compounds of lesser scope than the genus disclosed in a prior art reference on the basis of preferences ascertainable from the reference, anticipation may be found. Applicant also asserts that one in the art must "at once envisage" the claimed species. Applicant then asserts that the prior art does not provide the required "blaze marks" and assert that the methods of the prior art are drawn to "any organism". Applicant then asserts that the range of potential organisms is in the range of 20-30 million different organism and that both references assert that the size range can be 25-400 nucleotides for the double stranded RNA. First it is noted that applicants specification contains essentially the same list of potential organisms, in fact the disclosure of cell/organisms of the instant specification at pages 21-22 is essentially verbatim of the disclosure of Fire et al at column 8. The instant specification provides for dsRNA of from 20 to 800 bases in length where the instant claims, other than claim 49, are not limited to any size. So applicants assertions of the quantity of potential size range is clearly not on point.

Importantly the references do specifically name "human". This would tend to be a blaze mark in the opinion of the examiner. Applicants arguments that one in the art would not immediately envisage embodiments that target human genes is not plausible. One of the biggest goals of science is to benefit the human condition and make products to make a profit on the treatment of human disease.

Applicant then argues that the references are not enabled. Applicant cites Fire [TIG Vol. 15: 358-363, 1999] and asserts that Fire has made an admission of non-enablement. It is noted that the context of the cited passage is speculative and does not provide any evidence, and in fact states that there is no evidence, that the invention described in the prior art references are not enabled. It is noted that the prior art has provided guidance for expression in mammalian cells and applicant has not provided any evidence that the disclosure of the prior art is not enabled. Applicant argues the references as if the claimed invention is in the context of an animal where the claimed invention is in cells in culture. Applicant appears to require the prior art teach more than the instant specification which does not provide evidence any further than cells in culture. Indeed in the reference that applicant next cites, Wianny et al [Nature Cell Biology Vol. 2, 2000] which itself cites the Fire TIG reference states "[t]hus it appears that the concerns that RNAi may not work in the mouse **may have been raised prematurely**" (emphasis added). It is disclosed in that reference that siRNA constructs did not produce a significant PKR response and surely indicates that applicants concerns over PKR appear to be off point. Again the prior art teaches the claimed structure. Applicant appears to indicate that their invention does not invoke a PKR

response and the art appear to indicate a lack of PKR response and furthermore the context of the invention is in cells in culture. Applicant has provided no evidence or scientific reasoning to show how the prior art constructs would be so hard to use while applicants equivalent constructs would not.

It is noted that applicants reliance on the Wianny reference appears to be out of context since it appears that the "that RNAi might not work in mouse" is pulled from the text cited above, where the portion emphasized by the examiner was ignored, which would be contrary to applicants contentions.

Applicant makes a bald statement that the prior art contains an exceedingly large and impermissible number of combinations that are inoperative. Applicants' opinion is not supported by a lick of evidence or even sound scientific reasoning, but is merely a statement of belief.

Although it is noted that applicant may have provided elucidation of the mechanisms by which the compounds of the prior art function, such knowledge of the mechanisms was not needed to use the compounds as the prior art has asserted that they can be used. Applicant has not shown how the understanding of an underlying mechanism is required to perform the claimed invention. Applicant asserts that it is only with the instant specification that one in the art would know what cells/organismsRNA interference is possible. Again it is brought to applicants attention that the instant specification contains essentially the same list of potential organisms, in fact the disclosure of cell/organisms of the instant specification at pages 21-22 is essentially verbatim of the disclosure of Fire et al at column 8. It would appear that applicants'

specification provides evidence that indeed the list of organisms and cells of Fire et al was accurate. Applicants submission that "the only way that one could read the '559 patent as teaching a dsRNA to attenuate expression in a mammalian cell culture would be if one did not understand the literature" is appreciated, but not convincing. One can Read the claims of Fire et al in view of the specification of Fire and make a different and reasonable conclusion. Both pieces of prior art clearly teach expressing hairpins in mammalian/human cells to inhibit expression of an endogenous gene. It is unclear how applicant claimed invention differs from what has been disclosed by the prior art. Applicant surely has not shown the examiner how their claimed invention escapes a PKR response by a mechanism different from the prior art, especially in cells in culture. Applicant has cited many references and argued them as if they or there disclosure was in the instant specification. It is unclear what specifically in the instant specification one in the art would have used to overcome all of the concerns applicant has over the prior art when the instant specification provides the same scope of potential cell/organisms and the same size ranges of dsRNA lengths and even similar ranges of potential vectors and promoters. How would one in the prior art have know which of applicants embodiments would provide for what applicant asserts the prior art lacks. The examiner is at a loss to find such disclosure, but would certainly consider it if such a disclosure of the specification is specifically pointed to.

Applicant submits a declaration, filed initially 8/11/05, again on 3/09/07 and perfected 6/28/07 to antedate the Li reference. The below was indicated in the previous Official Action and not addressed by applicant in their response:

. The declaration, as it pertains to the invention now claimed, lacks convincing or sufficient evidence such that prior possession would be shown. The declaration and accompanying exhibits fails to show a hairpin expressed from a vector. The declaration and exhibits fail to show inhibition in cells where an shRNA is expressed from a vector. The declaration and exhibits fail to show mammalian cells in culture.

Exhibit D,with a small inset of "Redacted" set therein, is still not legible. Exhibit D provides no meaningful evidence as it appears in the IFW.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9, 10, 12, 14, 15, 28, 47, and 48 are rejected 35 U.S.C. 103(a) as being unpatentable over Graham [US 6,573,099 B2].

Graham discloses a method of delaying or repressing the expression of a target gene in an animal cell comprising transfecting the cell with a genetic construct wherein the construct comprises at least two copies of a structural gene sequence, wherein the gene sequence comprises a nucleotide sequence that is identical to at least a region of the target gene, and wherein the at least two copies of the structural gene are placed operably under the control of a single promoter sequence which is operable in the cell, wherein at least one copy of the structural gene sequence is placed operably in the sense orientation under the control of the promoter and where at least one other structural gene sequence is placed operably in the antisense orientation under the control of the promoter [claims 3, 7-9 and 18, for example]. The target genes include endogenous as well as foreign genes [column 4, line 40- column 5, line 6, for example]. Preferably the multiple structural gene unit comprises two structural genes in a head to tail or tail to tail or head to head configuration as an inverted repeat or palindrome [column 11, lines 3-63, and Figures 14 and 15, and Example 3].

Graham et al do not specifically disclose inhibition in cells suspended in culture, mammalian, primate or human cells specifically. However the invention described by

Graham et al is for the inhibition of targeted genes in an organism to defend against infection of viruses and also to treat disease. It would have been obvious to one in the art that mammalian, primate and human cells are clearly comprised in the scope of the teachings of Graham since, for example, one in the art would be most interested in treating diseases in human beings and since it was widely known in the art at the time of invention that many cancers, for example, are caused by endogenous genes [mutated or aberrantly expressed, for example] it would have been particularly obvious to target human genes. It clearly would have been obvious for one in the art to perform the inhibition methods in cells in culture before the use of the methods in cells in an organism such as a human since one in the art would have recognized the savings in cost and further since one in the art would clearly be required to test such methods in an appropriate cell and animal model before testing in a human, for example.

The invention as a whole would therefore have been *prime facie* obvious to one in the art at the time the invention was made.

Grahams teachings meet all of the structural limitations for the compounds required in the instant method claims. Any functional limitations such as being a substrate for RNAse III/Dicer, not producing a general sequence independent killing in mammalian cells (PKR response) and inhibition by at least 5 fold are presumed by the examiner to be present in the structures disclosed by Graham et al since they meet all of the structural requirements of the claims. If applicant believes that there is/are specific structures that provide for these properties of the claimed method and are not

disclosed by the prior art applicant should point to those structures of their claimed invention as they pertain to mammalian cells.

Applicant is reminded:

> **A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION,
> AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE
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> **"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).**
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> **Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). AWhen the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.≅ *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.**

**A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE
PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC**

**Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35
U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.**

Applicant argument appear to based on the expectation of success of inhibiting a gene via hairpin expressed from a vector. Applicant seems to argue as if the mode of inhibition must be by RNAi. Although, the examiner does not indicate that the prior art does not function by such a mechanism, the prior art does not require their invention function by an underlying mechanism elucidated by applicant. Applicant own claims are not even limited to RNAi. Applicant argues that there would be not expectation of success in what the prior art indicates will work. Applicant has provided no evidence that the constructs taught by the prior art will not function as the prior art says they will. Applicant contrary belief is not sufficient to deny the prior art. Applicant cites Wianny et al again and applicant is again reminded that their use of the reference appears to be contrary to that actually stated in the reference. Applicant appears to be "cherry picking" statement from the reference and ignoring the context of its actually disclosure. Wianny could be viewed in the following context. Not all believed that RNAi would function in mammalian cells. Some in the art did (the prior art applied in this Official Action, for example). Wianny et al showed that RNAi does work in cells without PKR response. The references cited in the Official Action appear to have been correct.

Applicant argues that secondary considerations should be considered. Among these is the teaching of applicant about PKR. Applicant is invited to show the examiner where in the specification this has been demonstrated in view of the claimed invention. Applicant asserts that hairpins generally exhibit better reassociation kinetics in cells that duplex RNA and that transgenic cell line can be made to express hairpins. It is unclear

what this has to do with the claimed invention is so far a secondary considerations of non-obviousness. Applicant is not claiming transgenic cells and it is unclear what the *unexpected* benefit of better reassociation kinetics in cells has in the context of the instant invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Sean R. McGarry/ whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean R McGarry/
Primary Examiner
Art Unit 1635